Remarks

Reconsideration and withdrawal of the rejections, in light of the arguments presented herein, is respectfully requested. Claims 1-4, 6-8, 11, 12, 14, 16, 18, 22, 109 and 110 are amended. Claims 1-24, 48 and 100-110 are currently pending.

Interview Summary

Applicant's Representative thanks Examiners Cheu and Chin for extending the courtesy of conducting an interview with Dr. Michael C. Flickinger, Ann M. Mueting (Reg. No. 33, 977) and Leif T. Stordal (Reg. No. 46,251) on 29 June 2004. Applicants note that Examiner Chin participated in the interview in place of Supervisory Patent Examiner (SPE) Long V. Le who had been supervising the prosecution of the case. Accordingly, Applicants respectfully request that the finality of the last Office Action be withdrawn in the next Official Communication to allow for an additional interview if necessary. Applicants further submit that Examiner Chin stated that arguments and amendments presented in the present response would be considered and entered respectively. In addition, Examiner Chin indicated that prosecution would be reopened.

Applicant's Representative thanks the Examiners for their understanding with regard to the interruptions that occurred during the interview due to difficulty experienced with the USPTO telephone system. These interruptions may have contributed to some confusion between the Examiners and the Applicant's Representative that occurred during the interview.

During the interview, numerous aspects of the invention and the cited art (in general) were discussed. One of these aspects included a discussion of "metabolically active" in which the cells of the invention were distinguished from certain cells described in the cited art. In the Interview Summary transmitted by facsimile on 29 June 2004, the Examiner stated with regard to the "'Metabolically active' issue, applicant considers that the prior art teaches sensor detection oxygen consumption is not a metabolic active type compared to the instant invention where protein synthesis, DNA synthesis is generated." Applicant's Representative disagrees with the Examiner's characterization of what was attempted to be communicated regarding "metabolically

active" and apologizes for any confusion. Applicants would like to clarify that the cells of the invention have the ability to carry on metabolic activities which are exemplified by (1) gene expression, (2) protein synthesis, (3) ATP production, (4) production of reducing equivalents such as NADH, NADPH and FADH, (5) DNA or RNA synthesis and replication, and (6) the ability to be recovered as viable cells, as opposed to cells which merely catalyze enzymatic reactions, for example. Accordingly, cells of the invention can carry on numerous metabolic activities. Applicants also emphasize that the cells of the invention are metabolically active when in combination with a nonporous latex-derived material. Although the art may teach oxygen-consuming cells, as in Thiagarajan et al., European Federation of Biotechnology, 11:304-312 (1995), for example, the combination of metabolically active cells in a nonporous latex material is not found in the cited art.

The 35 U.S.C. § 112, Second Paragraph, Rejections

The Examiner rejected claims 1-4, 11-16, 18, 22, 109-110 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleges that the phrase "latex-derived material formed by coalescence of latex-derived polymer particles" is vague and indefinite.

Applicants have amended claims 1-4, 11, 12, 14, 16, 18, 22, 109 and 110 to delete the phrase "formed by coalescence of latex-derived polymer particles" from the claims. Applicants respectfully submit that amendment of the claims renders the rejections moot. Accordingly, reconsideration and withdrawal of the rejections of the claims under 35 U.S.C. § 112, second paragraph, is proper and is respectfully requested.

The 35 U.S.C. § 102 Rejections

The Examiner rejected claims 1, 2, 6, 7, 9-13, 15, 18, 22, 48, 100-105, 107-110 under 35 U.S.C. § 102(b) alleging that the claims are anticipated by Thiagarajan et al., European Federation of Biotechnology, 11:304-312 (1995). This rejection is respectfully traversed.

Thiagarajan teaches a thin film plug reactor (TFPR) that can be used to study the physiology of *E. coli* that are permanently immobilized in thin films made from a latex copolymer of acrylic and vinyl acetate (pages 304 and 306). The TFPR consists of a glass chamber that contains an aluminum plug whose surface is coated with a mixture of copolymer and *E. coli* cell paste using a drawdown method (page 305). An alternative method uses cell + polymer-coated pressure sensitive polyester attached to the aluminum plug (page 305).

The Examiner refers to Figure 2 for the disclosure of a nonporous latex. However, Figure 2 is an illustration of a drawdown method used to coat aluminum plugs. Figure 2 shows how a slurry of bacteria and non-toxic latex copolymer of acrylic/vinyl acetate was applied to a coating plate assembly for coating onto aluminum plugs. Although the aluminum plugs are nonporous, the copolymer is not described as being nonporous (pages 306-308 and Figure 2).

The plug reactor was described as being a model system for designing porous immobilization media and bacterial cells to sustain biocatalytic activity for long periods of time (page 312). The films used within a TFPR are described as exhibiting diffusion properties that are related to polymer particle coalescence and film structure, which further indicates the porous nature of the films, as diffusion would not occur through a nonporous film. Thiagarajan used the TFPR to study oxygen uptake from medium that was in contact with the film of the TRPR.

Claims 1, 2, 11, 12, 18, 22, 109 and 110 are directed to a composite biological device comprising a biostructure comprising at least one biological material .... wherein at least a portion of the biostructure comprises a nonporous latex-derived material.

Claims 48, 100-105 and 107-108 are directed to a method of determining the presence of an analyte in a sample ..... upon contact with the analyte, the biological material produces a

response and emits a signal; and detecting the signal. Furthermore, the methods include use of a device that comprises a nonporous latex-derived material.

Thiagarajan does not teach a device that includes a nonporous material (claims 1, 2, 11, 12, 18, 22, 109 and 110). In addition, Thiagarajan does not teach a method to determine the presence of an analyte, or a method wherein a biological material produces a response and emits a signal upon contact with an analyte (claims 48, 100-105 and 107-108). Therefore, Applicants respectfully submit that Thiagarajan does not anticipate the claims and reconsideration and withdrawal of the rejections of the claims under 35 U.S.C. § 102(b) is respectfully requested.

The Examiner rejected claims 1, 4-10, 14-15, 18-20, 100-110 under 35 U.S.C. § 102(b) alleging that the claims are anticipated by Cantwell et al. (EP 0288203). This rejection is respectfully traversed.

Cantwell teaches immobilized cells in which bacterial or fungal cells are immobilized in intimate admixture with a solid organic polymer, and to processes for the preparation and use thereof (page 2, lines 3-5). The structure and permeability to aqueous media of the compositions "is such that a substrate is allowed access to the cells containing the enzyme to which it is to be subjected; a composition allowing suitable water permeability is used, e.g. acrylates are often preferred to polyvinylidene chloride (which tends to be a barrier to H_2O)" (page 4, lines 47-50). Cantwell further emphasizes that the advantages of their process are such that cells ... "(ii) retain their enzyme activity, (iii) be sufficiently porous to allow liquid access to the cells through the matrix" (page 6, lines 10-13). Thus, Cantwell teaches the preparation of porous compositions that allow a substrate to come into contact with a cell and thereby teaches away from nonporous compositions that would be a barrier to water permeability.

Applicants assert that Cantwell teaches immobilization of cells that retain their enzyme activity. However, Cantwell does not teach immobilization of cells that are metabolically active. Metabolism is defined as, "the sum of all the physical and chemical processes by which living organized substance is produced and maintained (anabolism), and also the transformation by

which energy is made available for the uses of the organism (catabolism)" (Dorland's Illustrated Medical Dictionary, W.B. Saunders Company, Philadelphia, USA, 28th edition, page 1020, see Exhibit A attached hereto). Cantwell is completely silent with regard to whether cells contained within the compositions as taught by Cantwell are metabolically active.

Claims 1, 2, 11, 12, 18, 22, 109 and 110 are directed to a composite biological device comprising a biostructure comprising at least one biological material ..... wherein at least a portion of the biostructure comprises a nonporous latex-derived material ..... wherein the biological material is metabolically active or that becomes metabolically active.

Claims 100-108 are directed to a method of determining the presence of an analyte in a sample that includes use of a device that comprises a nonporous latex-derived material and a biological material that is metabolically active or that becomes metabolically active.

Cantwell does not teach (i) a device that includes a nonporous material or a biological material that is metabolically active or that becomes metabolically active (claims 1, 2, 11, 12, 18, 22, 109 and 110) or (ii) a method that utilizes such a device (claims 100-108). Therefore, Applicants respectfully submit that Cantwell does not anticipate the claims and reconsideration and withdrawal of the rejections of the claims under 35 U.S.C. § 102(b) is respectfully requested.

The Examiner rejected claims 1-3, 6-22, 48, and 100-110 under 35 U.S.C. § 102(a) alleging that the claims are anticipated by Nova et al. (U.S. Patent No. 5,571,629). This rejection is respectfully traversed.

Nova teaches a combination that includes matrices with memories which contain matrix materials with remotely addressable or remotely programmable recording devices that contain at least one data storage unit (Abstract). The combination of matrix with memory is used by contacting it with, linking it to, or placing it in proximity with a molecule or biological particle, such as a virus or phage particle, a bacterium or a cell, to produce a second combination of a matrix with memory and a molecule or biological particle (column 6, lines 30-36). Nova defines a matrix as any solid or semisolid or insoluble support to which the memory device and/or the

molecule of interest, typically a biological molecule, organic molecule or biospecific ligand is linked or contacted (column 10, lines 49-52; column 17, lines 40-45 and column 18, lines 5-7). Nova teaches that the most commonly used methods that can be used to immobilize proteins and other biomolecules onto a support are absorption and adsorption or covalent binding to the support, either directly or via a linker (column 20, line 43 to column 21, line 26). Nova does not teach a matrix in which a biological material is an integral component thereof.

The Examiner alleges that Nova teaches metabolically active cells and a composition that includes a nonporous latex channel (citing column 6, lines 15-36 and Figure 7) (page 4 of the Office Action mailed 19 April 2004). Applicants respectfully request the Examiner to specifically indicate where Nova teaches metabolically active cells and nonporous latex-derived materials.

Applicants submit that Nova is completely silent with regard to any nonporous latex-derived material and to the metabolic status of any biological particle used in conjunction with a combination as taught by Nova. In addition, Nova teaches a combination on which a biological material is absorbed, adsorbed or linked to a matrix in contrast to a composite device in which a biological material is an integral component.

Applicants respectfully assert that Nova does not teach (i) a device that includes a nonporous latex-derived material and that comprises at least one biological material as an integral component thereof or a biological material that is metabolically active or that becomes metabolically active (claims 1-3, 11, 12, 14, 16, 18, 22, 109 and 110) or (ii) methods that utilize such a device (claims 100-108). Therefore, Applicants respectfully submit that Nova does not anticipate the claims and reconsideration and withdrawal of the rejections of the claims under 35 U.S.C. § 102(b) is respectfully requested.

The 35 U.S.C. § 103 Rejection

The Examiner maintained the rejection of claims 23-24 under 35 U.S.C. § 103(a) alleging that the claims are unpatentable over Nova et al. (U.S. Patent No. 5,571,629) in view of Wagner et al. (U.S. Patent No. 6,475,808). This rejection is respectfully traversed.

Wagner teaches arrays on which multiple proteins are immobilized and methods for their use (Abstract and column 9, line 12).

Applicants respectfully submit that Wagner does not teach a nonporous latex-derived material or biological material that is metabolically active or that becomes metabolically active.

Nova and Wagner, alone or in combination, do not teach a device that includes a nonporous latex-derived material or a biological material that is metabolically active or that becomes metabolically active. Accordingly, Applicants respectfully submit that Nova in view of Wagner does not render the claims 23-24 obvious and reconsideration and withdrawal of the rejections of the claims under 35 U.S.C. § 103 is respectfully requested.

Summary

It is respectfully submitted that the pending claims 1-24, 48 and 100-110 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
LYNGBERG et al.

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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 9th day of July, 2004, at 2:55 pm (Central Time).

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